11th Semi-Annual

DIAGNOSTIC **COVERAGE** & REIMBURSEMENT

DECEMBER 4-5 | BOSTON, MA

Aligning Payer Networks' Specific Needs with Diagnostic Development to Facilitate Expedited Reimbursement & Access to Alternate Payment Models, Focus on Clinical Study Design Enabling Generation of Actionable Evidence & Highlighting Clinical Utility, while Advancing on Value Based Care & Risk Sharing Applied to Diagnostics

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DEDICATED TO QUALITY FIRST™

11TH SEMI-ANNUAL

DIAGNOSTIC COVERAGE & REIMBURSEMENT

DECEMBER 4-5, 2017
BOSTON, MA

DISTINGUISED PRESENTERS INCLUDE:

PAYERS:

David Hochheiser
SVP, Provider Networks & Healthcare Value
BLUE CROSS BLUE SHIELD OF LOUISIANA

Akash Shah
Program Development & Innovation
CAREFIRST BCBS

Paul V. Aitkin Junior, MD, MPH, CPE, FAAFP
Senior Medical Director, Clinical Transformation
AETNA

Mary Stevens
Director of Network Contracting
BLUE CROSS BLUE SHIELD OF MINNESOTA

Jeff Mason
Former Senior Market Medical Director
UNITED HEALTHCARE

DIAGNOSTIC INDUSTRY EXPERTS:

Mark S. Girardi
Senior VP
GFK HEALTH

Vanessa DePalma
VP, Business Strategy & Payer Markets
MERIDIAN BIOSCIENCE

Michele Schoonmaker
VP Government Affairs
CEPHEID

Lena Chaihorsky
VP Payer Innovation
ALVA10

Philip Parks
Senior Director & Head of Medical Affairs
EXACT SCIENCES

Federico A. Monzon
Chief Medical Officer
CASTLE BIOSCIENCES

Jeffrey Bush
VP, Payer Markets & Reimbursement
ASSURERX HEALTH, INC.

Diane Johnson
VP Market Access & Reimbursement
EXACT SCIENCES

George Boswell Moseley III
Lecturer in Health Law & Management
HARVARD SCHOOL OF PUBLIC HEALTH

Jerry L. Garner
VP Payer Relations
BIO-REFERENCE LABORATORIES

Gordon Brown
Managing Partner
A&R CONSULTANTS LLC
Presented by **QUADAX, INC.**

Shivang Doshi
Manager
BOSTON HEALTHCARE ASSOCIATES

Stephanie P. Hales
Partner
SIDLEY AUSTIN

Joyce Gresko
Senior Associate
ALSTON & BIRD

Chandra N. Branham
VP, Payment & Health Care Delivery Policy
ADVAMED

Laurie Howard
VP Payer Policy & Relations
LABORATORY CORPORATION OF AMERICA
Pending

Mark Rayan
VP Managed Care & Reimbursement Strategy
MDXHEALTH

Jeffrey Jones
Executive VP, Commercial Operations
SKYLINE DX

Tom McLain
COO
EXOSOME DIAGNOSTICS
Pending

Lauren *Feldman*
Director
ADVI

CONFERENCE SPONSORS:

BOSTON HEALTHCARE ASSOCIATES · GfK · Hull Associates LLC MARKET ACCESS · LSA Larchmont Strategic Advisors · ADVI · Quadax Revenue Cycle Optimizers · ATELCOR · Premier Source AmerisourceBergen · QURE HEALTHCARE

AGENDA - DAY ONE - MONDAY, DECEMBER 4

7:45 Registration & Welcome Coffee

8:20 Chairpersons' Opening Remarks

8:30 OPENING ICE BREAKER: SHARING KEY COMPONENTS OF A ROBUST DIAGNOSTIC REIMBURSEMENT STRATEGY

The opening ice breaker will kick-off the event with an opportunity for all participants to move around the conference room with the goal of meeting other delegates and engaging in short and targeted discussion. In this interactive session, participants are encouraged to briefly share perspectives on the main drivers of an impactful and robust diagnostic reimbursement strategy, without delving into details nor proprietary information but rather highlighting key components that have benefited the company in obtaining successful reimbursement. Furthermore, participants in this warm-up session are also given the opportunity to build contacts with industry peers at the very start of the event, kicking off the program networking platform.

LEAD MODERATOR:
Kurt Matthes, TELCOR
MODERATORS:
Vanessa DePalma, MERIDIAN BIOSCIENCE
Jeffrey Bush, ASSURERX HEALTH, INC.

8:50 HEALTH POLICY RESEARCH & IMPACT ANALYSIS ON DIAGNOSTIC REIMBURSEMENT & MARKET ACCESS

As health policy continues to evolve at both the national and international levels, diagnostic manufacturers must ensure that tests remain at the forefront of importance, and meet the needs of value-driven care models. As such, recognizing trends in health policy as well as forecasting the potential impact of varied scenarios is of the utmost importance in preparing for times of continued change. Analysis of existing health policy research and the follow-on impact on diagnostic testing, from genetic testing to at home, point-of-care testing will provide executives with a forward thinking outlook on market access for the future.

George Boswell Moseley III, *Lecturer in Health Law & Management*
HARVARD SCHOOL OF PUBLIC HEALTH

9:20 PAYER ROUNDTABLE: PERSPECTIVES ON DIAGNOSTIC REIMBURSEMENT

Reimbursement approvals are determined within each private payer organization through specific review mechanisms, creating confusion for reimbursement executives in terms of applicable evidence to exhibit. As payers will take into account Laboratory Benefit Management Provider and in-house HTA reviews to process the approval or decline, but also analyze cost-benefit ratios pertinent to the market's needs, diagnostic reimbursement executives must ensure a clear understanding of payer expectations and evidence requirements in order to develop comprehensive value pitches that will be relevant to decision-makers. In addition, with the recent and ongoing shift towards value-based reimburse-ment schemes, the industry is eager to obtain enhanced clarity on payers' perspectives of value demonstration and reimbursement approval processes.

MODERATOR:
Mark Rayan, MDXHEALTH
PANELISTS:
David Hochheiser, BLUE CROSS BLUE SHIELD OF LOUISIANA
Akash Shah, CAREFIRST BCBS
Jeff Mason, UNITED HEALTHCARE
Paul Aitkin, MD, AETNA

10:20 Coffee & Networking Break

10:45 CLARIFYING LABORATORY BENEFIT MANAGEMENT PROVIDER'S ROLE & COLLABORATION WITH INDUSTRY

With the continued increase in healthcare spending per capita, health insurers have been prompted to better control spending and unnecessary medical product use. Laboratory Benefit Management Providers-LBMPs offer services to insurers to ensure network access and reimbursement is granted solely to diagnostics that meet unmet patient needs, as well as innovative tests enabling significantly improved patient outcomes. To establish efficient collaborations between the industry and LBMPs, it is necessary to have a clear understanding of the position of benefit managers within the overall reimbursement decision-making process.

- LBMP diagnostic review mechanism
- Added value of LBMP in network management
- Practical approach to contracting with LBMPs

Jerry L. Garner, *VP Payer Relations*
BIO-REFERENCE LABORATORIES

11:15 COST EFFECTIVE & VALUE-BASED EVIDENCE DEVELOPMENT

One of the more significant barriers to obtaining coverage and reimbursement for a new or established advanced diagnostic is the high cost of evidence development establishing clinical relevance. Creative approaches and a multi-prong strategy are critical to successfully balance evidence development with budget limitations and internal/investor pressure to broadly launch commercially.

- Clearly defining and staying within intended use
- From study to publication:
  - Value-based utility
  - Traditional studies
  - Value-based contracting
- Advocacy through KOLs & relevant societies
- Relevant patient-level appeals

Gordon Brown, *Managing Partner*
A&R CONSULTANTS LLC
Presented by **QUADAX, INC.**

12:00 GFK HEALTH: CONSUMERIZATION OF CLINICAL LABORATORY TESTING & SERVICES IMPACT ON REIMBURSEMENT

- Direct-to-consumer laboratory testing & services:
  - Patient empowerment & consumerization trends
  - Opportunities in innovative access strategies
- Direct to consumer testing, at home testing & remote diagnostics
- Changes in consumer behavior impact on healthcare
- Examples & insights into innovations

Mark S. Girardi, *Senior VP,* **GFK HEALTH**

12:45 Luncheon for all speakers, sponsors & attendees

2:00 APPLICABILITY OF VALUE-BASED CARE & RISK SHARING AGREEMENTS TO DIAGNOSTIC TESTS

Private as well as public payer organizations are progressively turning towards value-based and risk sharing strategies for healthcare products including diagnostics, directly inspired by pharmaceutical reimbursement programs. Reimbursement executives must therefore revise strategies for the development and delivery of value pitches, now focusing on the position and impact of the diagnostic test in the overall healthcare value chain. The industry is in need of clarification and understanding of how to highlight benefits of products in value-based and risk sharing structures.

- Understanding value-based pricing in practice
- Diagnostics' position in the overall value chain
- Clarifying risk sharing as it relates to diagnostics
- Reaching an agreement with payer boards

Lena Chaihorsky, *VP Payer Innovation*, **ALVA10**
Mary Stevens, *Director of Network Contracting*
BLUE CROSS BLUE SHIELD OF MINNESOTA

2:45 NATURE, QUALITY & VOLUME OF EVIDENCE NECESSARY TO SUPPORT REIMBURSEMENT

With payer requests for meaningful scientific and economic data, reimbursement executives are commonly collecting evidence from clinical teams to ultimately support value dossiers. Forward-thinking corporations have initiated collaborations with clinical teams and continue to develop clinical studies integrating health economic outcomes to address and streamline preparation of value pitches. In this proactive effort, it is critical to clearly determine what type of clinical evidence can be used to demonstrate product effectiveness and cost-benefit ratios specific to the target market, in addition to the overall amount of data to convey to decision makers in order to establish and meet target evidence end-points.

Shivang Doshi, *Manager,* **BOSTON HEALTHCARE ASSOCIATES**

3:30 Coffee & Networking Break

4:00 CLINICAL STUDY DESIGNS ESTABLISHING CLINICAL UTILITY & ROBUST EVIDENCE

- Bridging the gap with clinical teams:
  - Study design impact on evidence generation
  - Educating clinical teams on evidence for reimbursement
- Defining clinical utlity & how to demonstrate it
- RCT & diagnostics: applicability & evidence relevance
- Results with cohort, prospective/restrospective & more
- Ideal study design & results for payers

Federico A. Monzon, *CMO,* **CASTLE BIOSCIENCES**

4:45 PANEL DISCUSSION: PEER–REVIEWED PUBLICATION VS. CLINICAL EVIDENCE

- Weighing publication against clinical testing:
  - Timelines
  - Budgets
  - Evidence acceptability
- Utilization of payer standards for publication & outcomes

Jeffrey Jones, SKYLINE DX
Jerry L. Garner, BIO-REFERENCE LABORATORIES
Michele Schoonmaker, CEPHEID

5:30 Closing Remarks & Day 1 Conclusion

AGENDA - DAY TWO - TUESDAY, DECEMBER 5

8:00 Registration & Welcome Coffee

8:20 Chairpersons' Opening Remarks

8:30 ADVAMED'S VALUE FRAMEWORK FOR ASSESSING BENEFITS OF DIAGNOSTICS
- Designed for use by multiple healthcare stakeholders
- The 4 key value drivers:
  - Clinical Impact
  - Non-clinical patient impact
  - Care delivery revenue & cost impact
  - Public/population impact
- Defining evidence as it relates to value

Chandra N. Branham, *VP, Payment & Health Care Delivery Policy*
ADVAMED

9:15 MASTER CLASS: IMPACTFULLY DEMONSTRATING VALUE IN RELATION TO THE TARGET POPULATION & TREATMENT
A critical challenge faced by reimbursement executives working towards accessing reimbursement for new diagnostics is to demonstrate value and ultimately prove the efficiency and usefulness of the product to healthcare payers, therefore positively influencing coverage decisions. There is often times a difference of perspectives between payers and industry when defining value, as while the first will focus on optimized patient outcomes and cost-savings, the second will frequently focus more on the test's additional benefits. To make an impact and stand-out in a competitive market, it is critical to adopt the payer's perspective when developing the value dossier and pitch, taking into account the insurer's focus areas.
- Highlighting HE market analysis & impactful metrics
- Impact of test on regimen decisions & full treatment
- Demonstrating economic benefits & savings

Diane Johnson, *VP Market Access & Reimbursement*
EXACT SCIENCES

Philip Parks, *Senior Director & Head of Medical Affairs*
EXACT SCIENCES

10:15 Coffee & Networking Break

10:45 SUCCESSFUL INDUSTRY & PAYER PARTNERSHIPS
Diagnostic reimbursement executives are continuously challenged by a variety of obstacles, most commonly relevant to product integration in a competitive market. In the effort of advancing life-improving tests to patients and HCPs, forward thinking companies have established proactive strategies to engage and directly collaborate with payers in order to facilitate, streamline and expedite access to reimbursement. This session will present industry and payer collaboration case studies, focusing on the practical steps taken to initiate and achieve the partnership as well as encountered pitfalls and lessons learned.

AETNA HEALTH PLAN & MERIDIAN BIOSCIENCE CASE STUDY: DIAGNOSTIC DEVELOPMENT TO MEDICAL POLICY COVERAGE & IMPLEMENTATION
- Diagnostic technology: What is important to Payers
- Guideline review & clinical benefits: Patient, physician, lab & payer
- Dossier, FDA, Palmetto, PAMA considerations
- Financial Impact: Commercial, Medicaid, ACO, 5 star metrics on re-admissions
- Medical Policy Development: Commercial & ACO
- Education: Dear Provider communication, lab outreach, web portal

Vanessa DePalma, *VP, Business Strategy & Payer Markets*
MERIDIAN BIOSCIENCE

Paul V. Aitkin Junior, MD, MPH, CPE, FAAFP
Senior Medical Director, Clinical Transformation
AETNA

11:15 CAREFIRST BCBS & EXOSOME DIAGNOSTICS CASE STUDY

Akash Shah, *Program Development & Innovation*
CAREFIRST BCBS

Tom McLain, *COO*
EXOSOME DIAGNOSTICS ***Pending***

11:45 Luncheon for all speakers, sponsors & attendees

1:00 ESTABLISHING PRACTICAL REIMBURSEMENT STRATEGIES: FOCUS ON TIMELINE & BUDGET
Many diagnostic corporations recognize it can take up to 5-6 years between diagnostic development and obtaining of reimbursement which, if not accounted for, can lead to pressure from hierarchy and company board members. This common pitfall in the overall reimbursement strategy must be addressed early, to ensure relevant budget is available to support coverage efforts and the necessary time to obtain positive decisions from payers. Further, disseminating a clear understanding of the reality of reimbursement timelines to CFO, CMO, CEO and board members will ensure a robust plan is set up front.
- Recognizing necessary time to generate the right evidence
- Communicating the required steps to hierarchy & board
- Calculating the budget to support time to reimbursement
- Robust planning from reimbursement strategy inception

Jeffrey Jones, *Executive VP, Commercial Operations*
SKYLINE DX

1:45 PANEL DISCUSSION: NEW ADMINISTRATION IMPACT ON DIAGNOSTICS COVERAGE & REIMBURSEMENT
- Trump administration effect on healthcare access & coverage
- Analyzing the impact of potential repeal & replace scenarios
- Comparing perspectives on further areas of anticipated change

Chandra N. Branham, ADVAMED
Stephanie P. Hales, SIDLEY AUSTIN
Joyce Gresko, ALSTON & BIRD
Laurie Howard, LABORATORY CORPORATION OF AMERICA
Pending
Lauren Feldman, ADVI
Michele Schoonmaker, CEPHEID

2:30 APPLICABILITY & UTILIZATION OF EXISTING CPT CODES FOR DIAGNOSTIC TESTS
While identifying and using the right CPT code is pivotal to obtain reimbursement of a diagnostic, the industry is continuously challenged with codes that often times do not directly apply. The AMA updates codes every year, though not specifically taking into account the differing nature of all diagnostic products such as IVD, genomic, companion, molecular etc. With the lack of alignment between existing codes and diagnostic categories, reimbursement professionals seek clarity in the use of a coding system only partially relevant to the industry's specific needs, to ultimately enable better identification and billing of products.
- Assessing which code is the best fit for each test
- Reacting to payer's objection to code applicability
- February 2017 PLA codes: industry reviews
- AMA efforts in diagnostic coding & draft legislation

Jeffrey Bush, *VP, Payer Markets & Reimbursement*
ASSURERX HEALTH, INC.

3:15 Closing Remarks & Conference Conclusion

SPONSORSHIP OPPORTUNITIES:

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:
- Reimbursement Consultants
- Market Access & Commercialization
- Health Economics & Outcomes Researchers
- Software Solutions
- Clinical Research Organizations
- Revenue Cycle Management
- Laboratory Management Solutions
- Clinical Research Organizations
- UDI Technology Specialists
- Quality Assurance Software Providers

11TH SEMI-ANNUAL
DIAGNOSTIC COVERAGE & REIMBURSEMENT

DECEMBER 4-5, 2017
BOSTON, MA

PRE-CONFERENCE WEBINARS

Week of November 27th -
Complimentary for conference participants!

11/29 - 11:30am EST
QUADAX WEBINAR: UNDERSTANDING PAYER EXPECTATIONS TO COVER AND REIMBURSE FOR YOUR TEST

Payers are willing to cover and reimburse an advanced diagnostic that impacts treatment decisions and improves patient outcomes while ensuring limited healthcare care dollars are being used in a cost-effective manner. It's important that the advanced diagnostics industry both understand and appreciate the payer's perspective, and expectations, when seeking coverage and reimbursement.

Gordon Brown
Managing Partner
A&R CONSULTANTS LLC
Presented by **QUADAX, INC.**

GFK HEALTH WEBINAR: INCORPORATING MARKET ACCESS INTO THE NEW PRODUCT DEVELOPMENT PROCESS

- Understanding clinical & economic evidence requirements early in the process
- Market Access considerations as a go/no go criteria for phase gate New Product Introduction process
- Examples & insights into market access considerations

Mark Girardi M.S.
Senior Vice President
GFK HEALTH

KEY SPEAKER HIGHLIGHT:

David Hochheiser
SVP, Provider Networks & Healthcare Value
BLUE CROSS BLUE SHIELD OF LOUISIANA

BlueCross BlueShield of Louisiana

David brings almost 20 years of experience within the healthcare industry with focus in the areas of analytics, reimbursement methodologies and alternative payment methodologies. The majority of David's time has been spent on the vendor and consulting side of the healthcare ecosystem providing services both to Health Plans as well as Providers. David joined Blue Cross Blue Shield of Louisiana in June of 2015 in the role of Vice President of Provider Reimbursement and Payment Innovation. He now holds the position of SVP, Provider Networks & Healthcare Value with responsibility for Alternative Payment Strategy, Reimbursement Methodology and Strategy as well as Provider Networks, Credentialing and Communications.

PREVIOUS ATTENDEES INCLUDE:

Global Head of Market Access & Economics, ABBOTT DIABETES
Vice President of Government Affairs, ACLA
National Sales Director, ACM GLOBAL CENTRAL LABORATORY
VP, Payment & Health Care Delivery Policy, ADVAMED
Senior Director, Reimbursement & Customer Care, AGENDIA
Senior Director, Commercial Development, ALERE TOXICOLOGY
Vice President of Clinical Services, ALIMETRIX
CCO, AMBRY GENETICS
VP, Managed Care, API
President, QURE, Professor UCSF/UCLA, APPLIED PROTEOMICS
National Account Manager, ASSUREX HEALTH
Dir. Global Product & Portfolio Strategy (GPPS), ASTRAZENECA
Director, Corporate Strategy, ATIVA MEDICAL
Senior Vice President, Clinical Operations, AVALON HEALTHCARE
VP, Strategic Development & Payor Relations, BAKO
As. Director Precision Medicines, BD
Vice President, Clinical Programs, BEACONLBS
VP, Reimbursement Strategy & Sales Ops, BIOCEPT
CEO, BIOCEPT
SE Region Manager - Payer Relations, BIO-REFERENCE LABS
Senior Director, Billing & Revenue Cycle, BIOTHERANOSTICS
Exec. Dir., Center for Clinical Effectiveness, BCBS
Interim SVP, Medical Economics, BCBS OF LOUISIANA
Regional Medical Dir., Clinical Quality & Network, BCBS OF CA
Senior Contractor Medical Director, CAHABA GBA
Chief Commercial Officer, CAREDX
CEO, CASTLE BIOSCIENCES
Chief Financial Officer, CHRONIX BIOMEDICAL INC.
Vice President, Payor Access, COMBIMATRIX
VP Health Plans (Managed Care/MAccess Strategy), COUNSYL
President, CRESCENDO BIOSCIENCE, INC
Chief Medical Officer, EVICORE HEALTHCARE
President and CEO, EXAGEN DIAGNOSTICS, INC
Chief Medical Advisor, GENOMEDX BIOSCIENCES
Chief Commercialization Officer, GENOMONCOLOGY
Senior Director, Market Access, GENOPTIX MEDICAL LABORATORY
Health, Market Access Director, Laboratory Services, GM
Senior Director, Reimbursement, GUARDANT HEALTH, INC
Corporate Medical Director, HEALTH DATA INSIGHTS
Vice President, Managed Care, HEALTHTRACKRX
Director, National Payer Strategic Alliances, HOLOGIC
Vice President, Global Market Access, ILLUMINA, INC
As. Director, Global HE & Pricing, JANSSEN DIAGNOSTICS
Chief Medical Officer, LABCORP
Sr Mger, Health Policy & Reimb. Affairs, LUMINEX CORPORATION
Chief Commercial Officer, MED FUSION
Sr Corp. Dir., Health Plan, Payer Markets, MERIDIAN BIOSCIENCE
CEO, MMF SYSTEMS
General Manager, Urology, MYRIAD GENETICS
Market Access Director, NANOSTRING TECHNOLOGIES
VP, Market Access & Business Ops, ONCOCYTE
Director, Reimbursement & Payer Relations, OPTUM 360
Senior Manager, Payer Relations, ORTHOFIX
Director, Reimbursement, PRECISION DIAGNOSTICS
SVP, Diagnostics Solutions, PRECISION FOR MEDICINE
CEO & Owner, PRECISION GENETICS
Vice President, PREMIER SOURCE
Exec. Dir., Payer Strategy & Reimbursement, PROMETHEUS LABS
Head, Global Market Access & Reimb., ROCHE SEQUENCING

FEB
6-7

SAVE THE DATE

Join us in San Diego, CA this February!

12TH SEMI-ANNUAL DIAGNOSTIC COVERAGE & REIMBURSEMENT

February 6 & 7, 2018 – San Diego, CA